REMARKS/ARGUMENTS

Claims 39-47 and 49-51 are pending in this application. Claims 39-47 have been amended for clarity to remove references to figures. Although the prior rejection under 35 U.S.C. §101 has been withdrawn, all claims remain rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. This rejection is respectfully traversed.

Rejections Under 35 U.S.C. §112, First Paragraph

Claims 39-47 and 49-51 were rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the enablement requirement. The Examiner says that "since the *in vitro* evidence provided is not predictive of an *in vivo* effect and since no conditions are known for which PRO335 could be used, it would require undue experimentation for the skilled artisan to use the invention." Applicants respectfully traverse this rejection.

Utility has been asserted for PRO335 as an immunostimulator for use in the treatment of diseases benefiting from the enhancement of immune response such as AIDS and further, for antagonists of PRO335 as immunosuppressors in graft-vs-host disease, autoimmune disease, etc. based on the positive result in an MLR assay. This utility pertains to the field of immunotherapeutics. The Examiner states that the MLR assay is not predictive of *in vivo* efficacy, and hence undue experimentation would be needed to use the invention. Applicants respectfully disagree. Just because experimentation maybe needed to practice the invention, such experimentation is not necessarily undue, and further, it does not mean that the art of immunotherapeutics as a whole is unpredictable. In fact, Applicants submit that the level of skill in the art of immunotherapeutics is very advanced that the skilled artisan would find that the experimentation needed in this instance, routine. In *In re Wands*, the courts concluded that the amount of experimentation needed was not undue in view of the direction and guidance provided by the Appellants and the level of skill in the art:

> "the court held that ....there was 'considerable direction and guidance' in the specification; there was 'a high level of skill in the art at the time the application was filed;' and all the methods needed to practice the invention were well known." 858 F.2d at 740, 8 USPQ2d at 1406; M.P.E.P. 2164.01(a)

The MLR assay is widely used and is considered a standard assay for testing drug candidates that are potential immunomodulators. Based on the positive MLR result of PRO335, Applicants' have created a reasonable expectation that PRO335 or its antagonists can be used *in vivo* for immune related conditions. While the outcome of *in vivo* tests is not certain, experimentation may be necessary to achieve a positive result, and the amount of such experimentation is not undue. In this regard, Applicants respectfully remind that the skilled artisan in the field of Immunology and Immunotherapeutics at the effective filing date (September 17, 1998), would likely be a person with a Ph. D. or M.D. degree, sometimes both and with extensive experience. Such a person would, in fact, find it routine to carry out *in vivo* analysis to determine whether PRO335 or its antagonists are useful in *in vivo* immune diseases, based on such directed guidance.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

All claims pending in this application are believed to be in prima facie condition for allowance, and an early action to that effect is respectfully solicited.

Please any additional fees, including any additional fees for extension of time, or credit overpayment to Deposit Account No. **08-1641** (Attorney's Docket No. **39780-1618 P2C46**). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: March 2, 2004

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